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| 10/648,464 | 08/25/2003 | James D. Ralph | F-286 | 8288 |
| 51640 SPINE MP LERNER, DAVID, et al. 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090 | 7590 06/05/2007 | | <div>EXAMINER</div> <div>BLANCO, JAVIER G</div> | |
| | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/648,464

Applicant(s)

RALPH ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16, 18, 20, 21 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16, 18, 20, 21, and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 13, 16, 21, and 24 in the reply filed on March 26, 2007 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 13, 16, 18, 20, 21, and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Xavier et al. (US 6,063,121 A).
4. As seen in Figures 1-5, Xavier et al. disclose an intervertebral spacer device (10) comprising first (20) and second (48) plate members, each having an external plate surface thereof, wherein an inner surface of one of said plate members comprises a ball-shaped structure (ball supporting member 42 + ball 46, or ball 46 by itself) extending therefrom and an inner surface of the other one of said plate members has a spring (**first interpretation:** socket supporting member 62 and socket 68; **second interpretation:** cushion 80; **third interpretation:** socket supporting member 62 + socket 68 + cushion 80; **fourth interpretation:** socket 68 by itself) affixed thereto, said spring having an opening/curvate volume (**first interpretation:**

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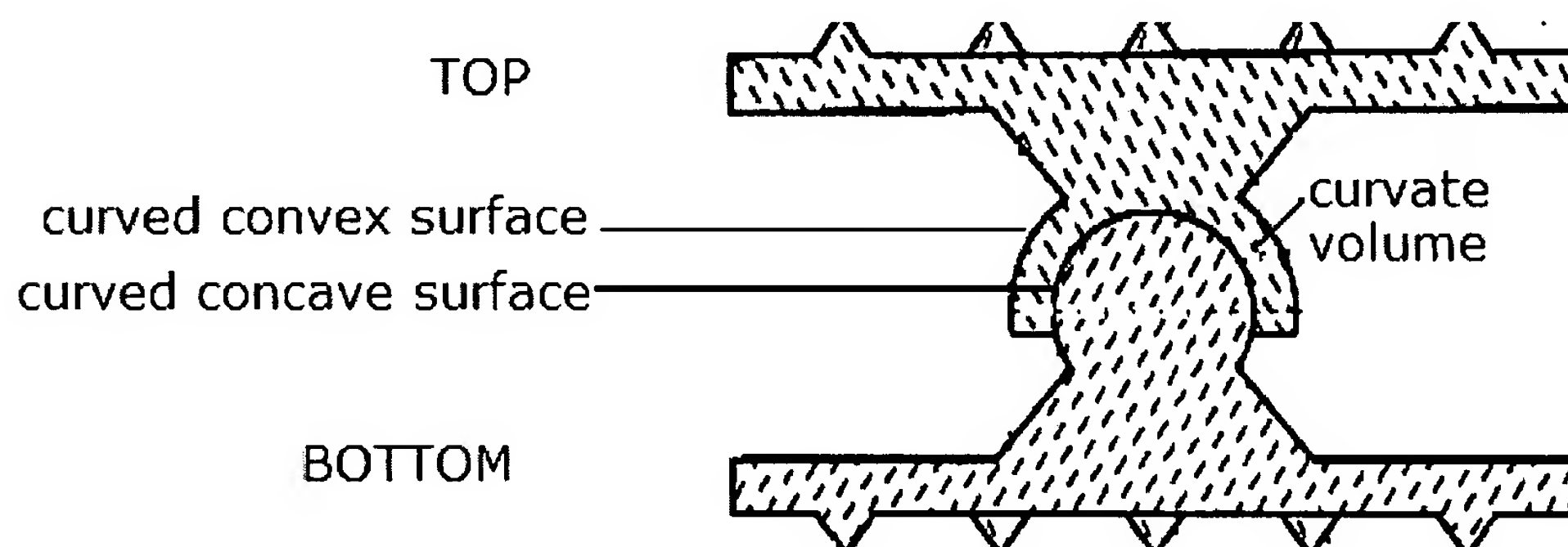
socket 68; **second interpretation:** central aperture 90; **third interpretation:** socket 68 + central aperture 90). Xavier et al. disclose socket supporting member 62, socket 68, ball supporting member 42, and ball 46 as made from either metal or ceramic (see column 4, lines 50-64), and able to counteract the load applied to at least one of the plate members (see column 4, lines 11-20). The spring/socket having a top side with a curved convex surface that extends from the curvate volume and confronts (i.e., face) the one of said plates and an underside with a curved concave surface that extends from the curvate volume and is spaced from and confronts (i.e., face) the other one of said plates.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Figure 5 of Xavier et al. '121 is shown below:



Response to Arguments

5. With regards to Xavier et al. '121, Applicants' arguments filed March 26, 2007 have been fully considered but they are not persuasive.

The Applicants argue that Xavier et al. '121 do not disclose newly added limitation: "said spring/socket having a top side with a curved convex surface that extends from the curvate volume and confronts the one of said plates and an underside with a curved concave surface that extends from the curvate volume and is spaced from and confronts the other one of said plates". The Examiner respectfully disagrees. See representation of Figure 5 of Xavier et al. '121 above. It should be noted the language is not specific as to which plates each of the "curved convex surface" and the "curved concave surface" is respectively facing.

6. Claims 13, 16, 18, 21, and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shima (US 5,534,029 A).

Referring to Figures 3-5, Shima discloses an intervertebral spacer device (21) comprising first/top (5) and second/bottom (4) plate members, each having an external plate surface thereof, wherein an inner surface of one of said plate members comprises a ball-shaped structure (ball 7) extending therefrom and an inner surface of the other one of said plate members has a spring/socket (body 20) affixed thereto, said spring having an opening/curvate volume (22) for receiving and holding therein (e.g., when assembled) said ball-shaped structure. The spring/socket having a top side with a curved convex surface (25) that extends from the curvate volume and confronts (i.e., face) the one of said plates and an underside with a curved concave

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surface (23) that extends from the curvate volume and is spaced from and confronts (i.e., face) the other one of said plates.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

7. Claims 13, 16, 18, 20, 21, and 23 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Ralph et al. (US 5,989,291; previously cited in PTO-892).

As seen in Figures 3b, 4, 5, and 7-9, Ralph et al. disclose an intervertebral spacer device comprising first and second plate members (e.g., 100a, 100b), each having an external plate surface (e.g., 102a, 102b) thereof, the plate members being disposed such that the external plate surfaces face in opposite directions. Ralph et al. disclose plate members 100a, 100b as convex (see column 2, lines 61-63) and as having a porous coating (see column 3, lines 4-6; column 5, lines 57-61). Additionally, Ralph et al. teach a porous, resilient/flexible (i.e., deflectable; see column 3, lines 8-18; column 6, lines 17-21), and convex (see Figures 4 and 9) fabric/mesh (circumferential wall 120) on an external lateral portion of the intervertebral spacer device (see Figures 4, 6, and 9). The ball attached with one of the plates is ball-shaped head 207. The spring/socket affixed with the other one of said plates is spring 230. The term “affixed” is

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commonly defined as “to secure to something”; “to fix one thing to another”. The spring/socket 230 will be affixed once the prosthesis is assembled since the assembly will prevent physical separation. As seen in Figures 8 and 9, the spring/socket having a top side with a curved convex surface that extends from the curvate volume 232/233 and confronts (i.e., face) the one of said plates and an underside with a curved concave surface that extends from the curvate volume and is spaced from and confronts (i.e., face) the other one of said plates.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Response to Arguments

8. With regards to Ralph et al. ‘2911, Applicants’ arguments filed March 26, 2007 have been fully considered but they are not persuasive.

The Applicants argue that Ralph et al. ‘291 do not disclose the socket/spring as “affixed” to the inner surface of one plate. The Examiner respectfully disagrees. The term “affixed” is commonly defined as “to secure to something”; “to fix one thing to another”. The spring/socket 230 will be affixed to the inner surface of one plate once the prosthesis is assembled since the assembly will prevent physical separation.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 14, 15, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xavier et al. (US 6,063,121 A) in view of Stubstad et al. (US 3,867,728 A; cited in Applicants' IDS).

Xavier et al. disclose the invention as claimed (see 102(b) rejection above). Xavier et al. did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable, convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9). Therefore, it would have been obvious to a person having

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ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Xavier et al., in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

11. Claims 14, 15, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al. (US 5,989,291; previously cited in PTO-892) in view of Stubstad et al. (US 3,867,728 A; cited in Applicants' IDS).

Although Ralph et al. disclose the external plate surfaces as convex to match the contour of the opposing bone surface (see column 2, lines 61-65), and a porous coating on said external plate surfaces to provide for tissue ingrowth (see column 3, lines 4-6; column 5, lines 57-61), they did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable,

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convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Ralph et al., in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

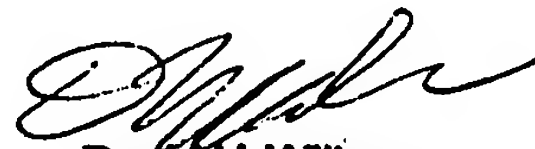
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

May 11, 2007



David H. Willse
Primary Examiner